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DECHERT LLP
P.O. BOX 10004
PALO ALTO, CA 94303

EXAMINER

PANNALA, SATHYANARAYA R

ART UNIT	PAPER NUMBER
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2177

DATE MAILED: 10/01/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/055,675

Applicant(s)

HOTCHKISS ET AL.

Examiner

Sathyanarayan Pannala

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 23 January 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-38 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-38 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 23 January 2002 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 2.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

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DETAILED ACTION

1. The Application 10/055675 filed on 1/23/2002 has been examined. Claims 1-38 are pending in this Office Action.

Information Disclosure Statement

2. The information disclosure statement (IDS) submitted on 08/08/2003 was filed in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement has been considered by the examiner.

Drawings

3. Examiner and Draftsperson object the drawings filed with the application, because, lot of the drawings are not readable, for example, see Fig. 7. Informalities indicated by Draftsperson are on the attached "Notice of Draftsperson's Patent Drawing Review," PTO-948. In order to avoid abandonment of this application, correction is required in reply to the Office action. The correction will not be held in abeyance.

Specification

4. The specification of the current invention is objected because the Background of the invention is missing. Further, the background consists of two sections, field of invention and Description of the Related Art. See MPEP § 608.01(c) and additionally information is as follows:

Background of the Invention: See MPEP § 608.01(c). The specification should set forth the Background of the Invention in two parts:

- (1) Field of the Invention: A statement of the field of art to which the invention pertains. This statement may include a paraphrasing of the applicable U.S. patent classification definitions of the subject matter of the claimed invention. This item may also be titled "Technical Field."
- (2) Description of the Related Art including information disclosed under 37 CFR 1.97 and 37 CFR 1.98: A description of the related art known to the applicant and including, if applicable, references to specific related art and problems involved in the prior art which are solved by the applicant's invention. This item may also be titled "Background Art."

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

6. Claims 1-38 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rienhoff, JR. et al. (USPA Pub., US2003/0208454) hereinafter Rienhoff and in view of Fagan et al. (USPA Pub., US2003/0110058) hereinafter Fagan.

7. As per independent claim 1, Rienhoff anticipated by disclosing a method and system for populating a database by gathering information from many individuals including family history, lifestyle, clinical and medical history, therapies and phenotype that is capable of being associated with biological sample (e.g., DNA information, etc.)

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from that individual. Such information can be aggregated and correlations uncovered to provide the basis for product development such as diagnostics, therapeutic selection, behavioral modification, drug discovery, etc (page 1, paragraph 0006). Rienhoff teaches the claimed “a computer system operable to service user requests and provide users with information responsive to the user requests” as the user computer 108 and the internet 106 may request of server system 102 health related information and in response, the server system 102 may dispense such health related information to the user computer 108 (Fig. 1, page 2, paragraph 0029). Further, Rienhoff teaches the claimed “a database coupled to the computer system, wherein the database is operable to store user data and study data and wherein the study data includes candidate data, specimen data, event data” as the system 100 includes a server system 102 coupled with a databases 104 and 105 (Fig. 1, page 2, paragraph 0028). Phenotypic data may be stored in a database 105 and the server system may invite user to submit biological sample to store on database (Fig. 1, page 2, paragraph 0039). In step 614, the user information may be entered into the registration from using the client device 108, information consists of name, address, phone number, email address, etc (Fig. 1, 6, page 7, paragraph 0082). Finally, Rienhoff does not explicitly teach defining a dataset using metadata. However, Fagan teaches the claimed “at least one dataset and wherein the dataset is defined using metadata” as the data being displayed in the window is the metadata that describes the protocol and datasets is used to merge the selected datasets and to display the individual variables (see Fagan, Fig. 9-10, page 3, paragraph 0035). Thus, it would have been obvious to one of ordinary skill in the data

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processing art to combine teaching of the cited references because Fagan's teachings would have allowed Rienhoff's system to create a dataset using metadata to include provisions for reengineering the data access and analysis (see Fagan, page 1, paragraph 0005).

8. As per dependent claim 2, Rienhoff teaches the claimed "the database is operable to store data related to scheduled (=punctual) [see page 4, paragraph 0044] events and unscheduled (=online) [see page 4, paragraph 0044] events" as online events relating to genetics, various health-related issues, diseases, medical conditions. Online events could be could be scheduled interviews on punctual basis (page 4, paragraph 0044).

9. As per dependent claim 3, Rienhoff teaches the claimed "the computer system is operable to send and receive electronic messages between at least two users" as the information could be directed to individual users via email or web pages viewable to group of users who have registered with the web site (Fig. 1, page 4, paragraph 0047).

10. As per dependent claim 4, Rienhoff teaches the claimed "the computer system is operable to limit communication of electronic messages between users having a specific role in connection with a specific study" as online event involves users, physicians, researchers and all these have specific role (see page 4, paragraph 0044).

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11. As per dependent claim 5, Rienhoff teaches the claimed “the candidate data includes data relating to a plurality of candidates and the specimen data includes data relating to a plurality of specimens wherein the system is operable to associate each specimen with a candidate” as inquiring for phenotypic data from each of a plurality of users, and inquiring biological material from a subset of the plurality of users.

Populating the database with genotypic data derived from received biological sample (page 1, paragraph 0009).

12. As per dependent claim 6, Rienhoff teaches the claimed “the user data includes at least one role associated with each user” as in step 610 a business concept is prompted by a web page may describe what will be done with information submitted by users, who will have the access to the information, the revenue sources of operators of the web site, the database, etc (page 7, paragraph 0080).

13. As per dependent claim 7, Rienhoff teaches the claimed “the user data includes at least one role associated with each user, wherein the role is selected from the group of data monitor, enroller, data editor, study administrator and system administrator” as developing trust is to provide users with control and privacy rights over information they submit to the web site, and make those rights known to the user (page 4, paragraph 0041).

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14. As per dependent claim 8, Rienhoff teaches the claimed “the role defines data access rights granted at a dataset definition level” as user may be given strict control in determining who may access information they have submitted which of the information may be accessed and in what form the information is provided to others (page 4, paragraph 0041).

15. As per dependent claim 9, Rienhoff teaches the claimed “the role defines data access rights granted at a data item definition level” as developing trust is to provide users with control and privacy rights over information they submit to the web site, and make those rights known to the user (page 4, paragraph 0041).

16. As per dependent claim 10, Rienhoff teaches the claimed “the role defines data access rights granted at a dataset definition level and data item definition level” as developing trust is to provide users with control and privacy rights over information they submit to the web site, and make those rights known to the user (page 4, paragraph 0041).

17. As per dependent claim 11, Rienhoff teaches the claimed “the database is operable to identify at least a portion of the user data as privacy data and wherein the role defines a users ability to view privacy data” as the users information may be provided to others in an aggregated form and which does not identify individual user (page 4, paragraph 0041).

18. As per dependent claim 12, Fagan teaches the claimed “the database includes at least one display form associated with the dataset and wherein the display form is defined using metadata” as the data being displayed in the window is the metadata that describes the protocol and datasets is used to merge the selected datasets and to display the individual variables as described by the dataset metadata both in terms of variable descriptors as well as measure definitions and groupings (Fig. 9-10, page 3, paragraph 0035).

19. As per dependent claim 13, Fagan teaches the claimed “the database includes at least two display forms associated with the dataset and wherein the display forms are defined using metadata” as the data displayed using database tables is different as the data being displayed in the window is the metadata that describes the protocol and datasets is used to merge the selected datasets and to display the individual variables as described by the dataset metadata both in terms of variable descriptors as well as measure definitions and groupings. The two displays will be different because the data presented to FDA is different from Product Release, for example, FDA approval phase 40 provides the additional data and uses the data collected and integrated from the previous phase to perform its analysis, whereas Product release the data relates to how the biomedical product is performing in the field (Fig. 1, 9-10, page 3, paragraph 0035 and page 2, paragraph 0020).

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20. As per dependent claim 14, Fagan teaches the claimed “a first display form is formatted to render the dataset on a first display device, and a second display form is formatted to render the dataset on a second display device” as the data displayed using database tables is different as the data being displayed in the window is the metadata that describes the protocol and datasets is used to merge the selected datasets and to display the individual variables as described by the dataset metadata both in terms of variable descriptors as well as measure definitions and groupings. The two displays will be different because the data presented to FDA is different from Product Release, for example, FDA approval phase 40 provides the additional data and uses the data collected and integrated from the previous phase to perform its analysis, whereas Product release the data relates to how the biomedical product is performing in the field (Fig. 1, 9-10, page 3, paragraph 0035 and page 2, paragraph 0020).

21. As per dependent claim 15, Fagan teaches the claimed “a first display form is formatted to render the dataset in a first language, and a second display form is formatted to render the dataset in a second language” as the data presented to FDA is different from the data presented to Product release and the languages used from one system to another system will be different and large pharmaceutical research firms provide different data access and analysis model (Fig. 1, page 2, paragraph 0020 and 0005).

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22. As per dependent claim 16, Fagan teaches the claimed “the database stores an audit record of data access including information relating to the data accessed, user, date and time” as FDA maintains the audit trail and it can be tracked down using the interrelationships 300 (Fig. 14, page 3, paragraph 0039).

23. As per dependent claim 17, Rienhoff teaches the claimed “at least a portion of the user data or study data is stored in the database in an encrypted format” as user may execute the informed consent from electronically via encryption (Fig. 7B, page 9, paragraph 0101).

24. As per independent claim 18, Rienhoff anticipated by disclosing a method and system for populating a database by gathering information from many individuals including family history, lifestyle, clinical and medical history, therapies and phenotype that is capable of being associated with biological sample (e.g., DNA information, etc.) from that individual. Such information can be aggregated and correlations uncovered to provide the basis for product development such as diagnostics, therapeutic selection, behavioral modification, drug discovery, etc (page 1, paragraph 0006). Rienhoff teaches the claimed step of “storing user data and study data in a database coupled to a computer system, wherein the study data includes candidate data, specimen data, event data and at least one dataset and wherein the dataset is defined using metadata” as phenotypic data may be stored in a database 105 and the server system may invite user to submit biological sample to store on database (Fig. 1, page 2,

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paragraph 0039). In step 614, the user information may be entered into the registration from using the client device 108, information consists of name, address, phone number, email address, etc (Fig. 1, 6, page 7, paragraph 0082). Finally, Rienhoff does not explicitly teach defining a dataset using metadata. However, Fagan teaches the claimed step of “defining a dataset using metadata” as the data being displayed in the window is the metadata that describes the protocol and datasets is used to merge the selected datasets and to display the individual variables (see Fagan, Fig. 9-10, page 3, paragraph 0035). Thus, it would have been obvious to one of ordinary skill in the data processing art to combine teaching of the cited references because Fagan’s teachings would have allowed Rienhoff’s system to create a dataset using metadata to include provisions for reengineering the data access and analysis (page 1, paragraph 0005).

25. As per dependent claim 19, Rienhoff teaches the claimed step of “the database is operable to store data related to scheduled (=punctual) [see page 4, paragraph 0044] events and unscheduled (=online) [see page 4, paragraph 0044] events” as online events relating to genetics, various health-related issues, diseases, medical conditions. Online events could be could be scheduled interviews on punctual basis (page 4, paragraph 0044).

26. As per dependent claim 20, Rienhoff teaches the claimed step of “the computer system is operable to send and receive electronic messages between at least two users” as the information could be directed to individual users via email or web pages

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viewable to group of users who have registered with the web site (Fig. 1, page 4, paragraph 0047).

27. As per dependent claim 21, Rienhoff teaches the claimed step of “the computer system is operable to limit communication of electronic messages between users having a specific role in connection with a specific study” as online event involves users, physicians, researchers and all these have specific role (page 4, paragraph 0044).

28. As per dependent claim 22, Rienhoff teaches the claimed step of “the candidate data includes data relating to a plurality of candidates and the specimen data includes data relating to a plurality of specimens wherein the system is operable to associate each specimen with a candidate” as inquiring for phenotypic data from each of a plurality of users, and inquiring biological material from a subset of the plurality of users. Populating the database with genotypic data derived from received biological sample (page 1, paragraph 0009).

29. As per dependent claim 23, Rienhoff teaches the claimed step of “the user data includes at least one role associated with each user” as in step 610 a business concept is prompted by a web page may describe what will be done with information submitted by users, who will have the access to the information, the revenue sources of operators of the web site, the database, etc (page 7, paragraph 0080).

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30. As per dependent claim 24, Rienhoff teaches the claimed step of “the user data includes at least one role associated with each user, wherein the role is selected from the group of data monitor, enroller, data editor, study administrator and system administrator” as developing trust is to provide users with control and privacy rights over information they submit to the web site, and make those rights known to the user (page 4, paragraph 0041).

31. As per dependent claim 25, Rienhoff teaches the claimed step of “the role defines data access rights granted at a dataset definition level” as user may be given strict control in determining who may access information they have submitted which of the information may be accessed and in what form the information is provided to others (page 4, paragraph 0041).

32. As per dependent claim 26, Rienhoff teaches the claimed step of “the role defines data access rights granted at a data item definition level” as developing trust is to provide users with control and privacy rights over information they submit to the web site, and make those rights known to the user (page 4, paragraph 0041).

33. As per dependent claim 27, Rienhoff teaches the claimed step of “the role defines data access rights granted at a dataset definition level and data item definition level” as developing trust is to provide users with control and privacy rights over

information they submit to the web site, and make those rights known to the user (page 4, paragraph 0041).

34. As per dependent claim 28, Rienhoff teaches the claimed step of “the database is operable to identify at least a portion of the user data as privacy data and wherein the role defines a users ability to view privacy data” as the users information may be provided to others in an aggregated form and which does not identify individual user (page 4, paragraph 0041).

35. As per dependent claim 29, Fagan teaches the claimed step of “the database includes at least one display form associated with the dataset and wherein the display form is defined using metadata” as the data being displayed in the window is the metadata that describes the protocol and datasets is used to merge the selected datasets and to display the individual variables as described by the dataset metadata both in terms of variable descriptors as well as measure definitions and groupings (Fig. 9-10, page 3, paragraph 0035).

36. As per dependent claim 30, Fagan teaches the claimed step of “the database includes at least two display forms associated with the dataset and wherein the display forms are defined using metadata” the data displayed using database tables is different as the data being displayed in the window is the metadata that describes the protocol and datasets is used to merge the selected datasets and to display the individual

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variables as described by the dataset metadata both in terms of variable descriptors as well as measure definitions and groupings. The two displays will be different because the data presented to FDA is different from Product Release, for example, FDA approval phase 40 provides the additional data and uses the data collected and integrated from the previous phase to perform its analysis, whereas Product release the data relates to how the biomedical product is performing in the field (see Fagan, Fig. 1, 9-10, page 3, paragraph 0035 and page 2, paragraph 0020).

37. As per dependent claim 31, Fagan teaches the claimed step of "a first display form is formatted to render the dataset on a first display device, and a second display form is formatted to render the dataset on a second display device" as the data displayed using database tables is different as the data being displayed in the window is the metadata that describes the protocol and datasets is used to merge the selected datasets and to display the individual variables as described by the dataset metadata both in terms of variable descriptors as well as measure definitions and groupings. The two displays will be different because the data presented to FDA is different from Product Release, for example, FDA approval phase 40 provides the additional data and uses the data collected and integrated from the previous phase to perform its analysis, whereas Product release the data relates to how the biomedical product is performing in the field (see Fagan, Fig. 1, 9-10, page 3, paragraph 0035 and page 2, paragraph 0020).

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38. As per dependent claim 32, Fagan teaches the claimed step of “a first display form is formatted to render the dataset in a first language, and a second display form is formatted to render the dataset in a second language” as the data presented to FDA is different from the data presented to Product release and the languages used from one system to another system will be different and large pharmaceutical research firms provide different data access and analysis model (see Fagan, Fig. 1, page 2, paragraph 0020 and 0005).

39. As per dependent claim 33, Fagan teaches the claimed step of “the database stores an audit record of data access including information relating to the data accessed, user, date and time” as FDA maintains the audit trail and it can be tracked down using the interrelationships 300 (Fig. 14, page 3, paragraph 0039).

40. As per independent claim 34, Rienhoff anticipated by disclosing a method and system for populating a database by gathering information from many individuals including family history, lifestyle, clinical and medical history, therapies and phenotype that is capable of being associated with biological sample (e.g., DNA information, etc.) from that individual. Such information can be aggregated and correlations uncovered to provide the basis for product development such as diagnostics, therapeutic selection, behavioral modification, drug discovery, etc (page 1, paragraph 0006). Rienhoff teaches the claimed “a computer system operable to service user requests and provide

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users with information responsive to the user requests” as the user computer 108 and the internet 106 may request of server system 102 health related information and in response, the server system 102 may dispense such health related information to the user computer 108 (Fig. 1, page 2, paragraph 0029). Further, Rienhoff teaches the claimed “a database coupled to the computer system, wherein the database is operable to store user data and study data relating to a plurality of studies, wherein study data includes candidate data, specimen data, event data” as the system 100 includes a server system 102 coupled with a databases 104 and 105 (Fig. 1, page 2, paragraph 0028). Phenotypic data may be stored in a database 105 and the server system may invite user to submit biological sample to store on database (Fig. 1, page 2, paragraph 0039). In step 614, the user information may be entered into the registration from using the client device 108, information consists of name, address, phone number, email address, etc (Fig. 1, 6, page 7, paragraph 0082). Further, Rienhoff teaches the claimed “at least one dataset, wherein user data includes at least one role associated with each user” as in step 610 a business concept is prompted by a web page may describe what will be done with information submitted by users, who will have the access to the information, the revenue sources of operators of the web site, the database, etc (page 7, paragraph 0080). Further, Rienhoff teaches the claimed “the role defines data access rights granted at one of a dataset definition level and data item definition level” as developing trust is to provide users with control and privacy rights over information they submit to the web site, and make those rights known to the user (page 4, paragraph 0041). Finally, Rienhoff does not explicitly teach defining a dataset

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using metadata. However, Fagan teaches the claimed “at least one dataset and wherein the dataset is defined using metadata” as the data being displayed in the window is the metadata that describes the protocol and datasets is used to merge the selected datasets and to display the individual variables (see Fagan, Fig. 9-10, page 3, paragraph 0035). Thus, it would have been obvious to one of ordinary skill in the data processing art to combine teaching of the cited references because Fagan’s teachings would have allowed Rienhoff’s system to create a dataset using metadata to include provisions for reengineering the data access and analysis (see Fagan, page 1, paragraph 0005).

41. As per independent claim 35, Rienhoff anticipated by disclosing a method and system for populating a database by gathering information from many individuals including family history, lifestyle, clinical and medical history, therapies and phenotype that is capable of being associated with biological sample (e.g., DNA information, etc.) from that individual. Such information can be aggregated and correlations uncovered to provide the basis for product development such as diagnostics, therapeutic selection, behavioral modification, drug discovery, etc (page 1, paragraph 0006). Rienhoff teaches the claimed “a computer system operable to service user requests and provide users with information responsive to the user requests” as the user computer 108 and the internet 106 may request of server system 102 health related information and in response, the server system 102 may dispense such health related information to the user computer 108 (Fig. 1, page 2, paragraph 0029). Further, Rienhoff teaches the

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claimed "a database coupled to the computer system, wherein the database is operable to store user data and study data relating to a plurality of studies, wherein study data includes candidate data, specimen data, event data" as the system 100 includes a server system 102 coupled with a databases 104 and 105 (Fig. 1, page 2, paragraph 0028). Phenotypic data may be stored in a database 105 and the server system may invite user to submit biological sample to store on database (Fig. 1, page 2, paragraph 0039). In step 614, the user information may be entered into the registration from using the client device 108, information consists of name, address, phone number, email address, etc (Fig. 1, 6, page 7, paragraph 0082). Further, Rienhoff teaches the claimed "user data includes at least one role associated with each user" as in step 610 a business concept is prompted by a web page may describe what will be done with information submitted by users, who will have the access to the information, the revenue sources of operators of the web site, the database, etc (page 7, paragraph 0080). Further, Rienhoff teaches the claimed "the computer system is operable to limit communication of electronic messages between user having a specific role in connection with a specific study the system" as the information could be directed to individual users via email or web pages viewable to group of users who have registered with the web site (Fig. 1, page 4, paragraph 0047). Finally, Rienhoff does not explicitly teach defining a dataset using metadata. However, Fagan teaches the claimed "at least one dataset and wherein the dataset is defined using metadata" as the data being displayed in the window is the metadata that describes the protocol and datasets is used to merge the selected datasets and to display the individual variables

(see Fagan, Fig. 9-10, page 3, paragraph 0035). Thus, it would have been obvious to one of ordinary skill in the data processing art to combine teaching of the cited references because Fagan's teachings would have allowed Rienhoff's system to create a dataset using metadata to include provisions for reengineering the data access and analysis (see Fagan, page 1, paragraph 0005).

42. As per independent claim 36, Rienhoff anticipated by disclosing a method and system for populating a database by gathering information from many individuals including family history, lifestyle, clinical and medical history, therapies and phenotype that is capable of being associated with biological sample (e.g., DNA information, etc.) from that individual. Such information can be aggregated and correlations uncovered to provide the basis for product development such as diagnostics, therapeutic selection, behavioral modification, drug discovery, etc (page 1, paragraph 0006). Rienhoff teaches the claimed "servicing user requests and providing users with information responsive to the user requests" as the user computer 108 and the internet 106 may request of server system 102 health related information and in response, the server system 102 may dispense such health related information to the user computer 108 (Fig. 1, page 2, paragraph 0029). Further, Rienhoff teaches the claimed "a database for storing user data and study data and wherein the study data includes candidate data, specimen data, event data" as phenotypic data may be stored in a database 105 and the server system may invite user to submit biological sample to store on database (Fig. 1, page 2, paragraph 0039). In step 614, the user information may be entered into

the registration from using the client device 108, information consists of name, address, phone number, email address, etc (Fig. 1, 6, page 7, paragraph 0082). Finally, Rienhoff does not explicitly teach defining a dataset using metadata. However, Fagan teaches the claimed “at least one dataset and wherein the dataset is defined using metadata” as the data being displayed in the window is the metadata that describes the protocol and datasets is used to merge the selected datasets and to display the individual variables (see Fagan, Fig. 9-10, page 3, paragraph 0035). Thus, it would have been obvious to one of ordinary skill in the data processing art to combine teaching of the cited references because Fagan’s teachings would have allowed Rienhoff’s system to create a dataset using metadata to include provisions for reengineering the data access and analysis (page 1, paragraph 0005).

43. As per independent claim 37, Rienhoff teaches a method and system for populating a database by gathering information from many individuals including family history, lifestyle, clinical and medical history, therapies and phenotype that is capable of being associated with biological sample (e.g., DNA information, etc.) from that individual. Such information can be aggregated and correlations uncovered to provide the basis for product development such as diagnostics, therapeutic selection, behavioral modification, drug discovery, etc (page 1, paragraph 0006). Rienhoff teaches the claimed “presentation creation means operable to provide users with dynamic information” as the user can access and retrieve data from a remote database via a computer network such as a LAN or the internet (Fig. 1, page 3, paragraph 0034).

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Further, Rienhoff teaches the claimed “application control and navigation means operable to service user requests” as the individual users accessing a web site and get the offered information on health-related issues and a variety of diseases and medical conditions (page 2, paragraph 0025). Further, Rienhoff teaches the claimed “data access means operable to access information that resides in a system database wherein the database is operable to store user data and study data and wherein the study data includes candidate data, specimen data, event data” as phenotypic data may be stored in a database 105 and the server system may invite user to submit biological sample to store on database (Fig. 1, page 2, paragraph 0039). In step 614, the user information may be entered into the registration from using the client device 108, information consists of name, address, phone number, email address, etc (Fig. 1, 6, page 7, paragraph 0082). Finally, Rienhoff does not explicitly teach defining a dataset using metadata. However, Fagan teaches the claimed “at least one dataset and wherein the dataset is defined using metadata” as the data being displayed in the window is the metadata that describes the protocol and datasets is used to merge the selected datasets and to display the individual variables (see Fagan, Fig. 9-10, page 3, paragraph 0035). Thus, it would have been obvious to one of ordinary skill in the data processing art to combine teaching of the cited references because Fagan’s teachings would have allowed Rienhoff’s system to create a dataset using metadata to include provisions for reengineering the data access and analysis (see Fagan, page 1, paragraph 0005).

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44. As per dependent claim 38, Rienhoff teaches the claimed "application and data security means operable to limit users access to information in the system database" as a tool for users to build a secure online medical record, providing users with secure, but convenient to use their own medical information and stored in database 105.

Additionally, users may give the option to let select others access their medical records (Fig. 1, page 4, paragraph 0046).

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sathyanarayan Pannala whose telephone number is (703) 305-3390. The examiner can normally be reached on 8:00 am - 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John Breene can be reached on (703) 305-9790. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

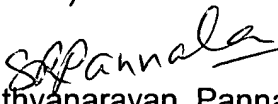
Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only.

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Sathyanarayan Pannala
Examiner
Art Unit 2177

srp
September 29, 2004